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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,631	02/15/2001	Jose A. Fernandez-Pol	42108.0106	2674

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EXAMINER

COPPINS, JANET L

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/784,631

Applicant(s)

FERNANDEZ-POL, JOSE A.

Examiner

Janet Coppins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 13-83 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-22, 24, 28-30, 32-24, 38-40, 43-83 is/are rejected.
- 7) ☒ Claim(s) 23,25-27,31,35-37,41 and 42 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### **DETAILED ACTION**

Claims 13-83 pending in the instant application.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/31/02 has been entered.

#### ***Response to Arguments***

2. Applicant's Amendment B, filed 9/3/02, has been reviewed and entered of record in the file as Paper No. 12, and the arguments have been fully considered. The Examiner appreciates the Applicant's correction of the claim to priority applications, and the Specification has been amended to clarify the continuity of priority documents. Accordingly, the instant application claims priority under 35 U.S.C. 119(e) to provisional patent application No. 60/182,608, filed 2/15/00.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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(a) Claims 13,18,21,39,43,47,48,53,54,58,59,63,69,70,74,75,78,79, and 83 previously rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling, and as containing subject matter which was not sufficiently described in the specification. The Applicant's arguments regarding the 35 U.S.C. 112, first paragraph rejections of said claims have been considered but are not persuasive. The Applicant claims "A peptide of sixteen amino acids," which is critical or essential to the practice of the invention, but said amino acids are not included in the claims and are not enabled or described by the disclosure. The Applicant asserts that the PTO has no concern over breadth of terms, and that the first paragraph of 35 USC 112 requires nothing more than objective enablement, however the specification fails to teach or fairly suggest any amino acids, including processes of making and/or using. The Examiner maintains the 35 U.S.C. 112, first paragraph rejections of the aforementioned claims, for the reasons of record, and since the Applicant has not overcome the enablement or scope issues. Neither the specification nor the claims provide any indication as to a single configuration or sequence of amino acids, and the broad terminology "a peptide of sixteen amino acids" covers thousands of compounds, which imposes more than routine experimentation on the skilled artworker. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

(b) Claims 13,18,21, and 39 previously rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating certain viruses, does not reasonably provide enablement for the treatment of all diseases associated with decreased immune function. In view of the amendatory changes to remove the phrase "decreased immune function" from the

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aforementioned claims, the Applicant has overcome the enablement rejections and the Examiner withdraws the 35 U.S.C. 112, first paragraph rejections of claims 13, 18, 21, and 39.

(c) Claims 13-47 and 59-83 previously rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(d) As a result of Applicant's amendatory changes and persuasive arguments, claims 13-20 now read as composition claims, claims 21-42 are method claims, and claims 43-69 read as composition claims. Thus the 35 U.S.C. 112, second paragraph rejections of claims 13-69 are obviated, and therefore are withdrawn. The Examiner would like to point out that while claims 13, 18, 48, 59, 63, 65, and 69, as amended, are now clearly composition claims, they also recite intended use, which bears no weight on the patentability of the claimed compounds or compositions

(e) Claims 70, 74, 75 and 78 previously recited percentages which were rejected under 35 U.S.C. 112, second paragraph for being vague and indefinite. In view of Applicant's amendments to remove the limitations in question, the 35 USC 112, 2<sup>nd</sup> paragraph rejections are withdrawn by the Examiner.

(f) Claims 79, 81, and 83 employ the term "contacting" in line 1, rendering the claims indefinite, as it is unclear if the two ingredients are physically contacted with each other or if they are reacted together thus causing a chemical reaction. The Applicant has failed to overcome the 35 U.S.C. 112, second paragraph rejections of said claims, as the arguments are non-persuasive and the amendments still render the claims indefinite for reciting the term

"contacting." Further, Applicant has amended claim 81 to include the previously rejected claim

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language "...in a concentration less than about 0.025% by weight..." which still reads on 0%, and is vague and indefinite.

(g) Claims 13,18,21,39,43,47,48,53,54,58,59,63,69,70,74,75,78,79, and 83 recite the phrase "a peptide of sixteen amino acids..." in the aforementioned claims are inoperative terms which render the claims indefinite. The "sixteen amino acids" which could be ascertained and combined to form the peptide are not listed or defined by the claims. The Examiner maintains the 35 U.S.C. 112, second paragraph rejections, for the reasons of record, as the Applicant has failed to specify a list of amino acids, or their configurations, which he intends to encompass in the broad terminology "a peptide of sixteen amino acids."

(h) Claims 71-73, 76, 77, 80, and 82 are previously rejected under 35 U.S.C. 112, as being dependent on rejected indefinite base claims. As the Examiner has maintained the rejections of the base claims, the aforementioned dependent claims remain rejected under 35 U.S.C. 112.

### *Claim Rejections - 35 USC § 102*

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 13-22, 24, 28-30, 32-34,38-40, 43-74, in part, previously rejected under 35 U.S.C. 102(b) as being anticipated by Otsu et al., US No. 5,582,817. The Applicant traverses the rejection. The Examiner respectfully maintains the 102 (b)-rejection. Otsu et al. teach picolinic acids according to formula I, metal salts and derivatives according to said formula, and amino

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acid and peptide derivatives of said formula, which read on the instant claimed metal chelating agent (see page 6). The Examiner would like to point out that while the Applicant has amended claims 13, 43, 48, and 59 to exclude zinc picolinate, the Otsu et al. patent reads on any metal salt of the instant claimed picolinic acid, not just zinc salts. The Applicant's arguments regarding Otsu et al. concern the methods of using the compounds according to Formula (I), however, the Applicant has previously asserted that Claims 13-20 and 43-69 are clearly composition claims, not method claims. Intended use of the instant claimed compounds and compositions bears no weight on the patentability of the invention.

In addition, the Examiner would like to respectfully point out again that claims 13, 18, 48, 59, 63, 65, and 69, as amended, are compound or composition claims, even though they recite intended use(s).

5. Claims 18, 20, and 39-43 in part, previously rejected under 35 U.S.C. 102(b) as being anticipated by Sherlock et al., US No. 4,138,488. Sherlock et al. disclose picolinic acids according to structural formula I, however, in view of Applicant's persuasive arguments, the Examiner drops the 35 U.S.C. 102 (b) rejections as anticipated by Sherlock et al.

#### ***Claim Objections***

6. Claims 23, 25-27, 31, 35-37, and 41-42 objected to as being dependent on rejected base claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Coppins whose telephone number is 703.308.4422. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703.308.4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703.746.9037 for regular communications and 703.872.9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.1235.

Janet L. Coppins  
November 17, 2002

  
**ALAN L. ROTMAN**  
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